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| APPLICATION NO.                                      | FI                   | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|------------------------------------------------------|----------------------|------------|----------------------|--------------------------|------------------|
| 10/620,704                                           | 0/620,704 07/17/2003 |            | Thomas P. Jerussi    | 4821-518-999             | 9314             |
| 20582                                                | 7590                 | 07/27/2004 |                      | EXAMINER                 |                  |
| JONES DA                                             | Y                    |            | KIM, JENNIFER M      |                          |                  |
| 51 Louisiana Aveue, N.W<br>WASHINGTON, DC 20001-2113 |                      |            |                      | ART UNIT                 | PAPER NUMBER     |
|                                                      |                      |            |                      | 1617                     | 1617             |
|                                                      |                      |            |                      | DATE MAIL ED. 07/27/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Application No.                                                 | Applicant(s)                |  |  |  |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-----------------------------|--|--|--|--|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 10/620,704                                                      | JERUSSI ET AL.              |  |  |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Examiner                                                        | Art Unit                    |  |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Jennifer Kim                                                    | 1617                        |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                 |                             |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                                                                 |                             |  |  |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                 |                             |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 30 Ju                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <u>ne 2004</u> .                                                |                             |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | )☐ This action is <b>FINAL</b> . 2b)⊠ This action is non-final. |                             |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                 |                             |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                 |                             |  |  |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                 |                             |  |  |  |  |  |
| 4) Claim(s) 14-27 and 37-44 is/are pending in the application.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                 |                             |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                 |                             |  |  |  |  |  |
| 5) Claim(s) is/are allowed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                 |                             |  |  |  |  |  |
| 6) Claim(s) <u>14-27,37-44</u> is/are rejected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                 |                             |  |  |  |  |  |
| 7) Claim(s) is/are objected to.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                 |                             |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                 |                             |  |  |  |  |  |
| Application Papers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                 |                             |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                 |                             |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acce                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                 | Examiner.                   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                 |                             |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                 |                             |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                 |                             |  |  |  |  |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                 |                             |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                 |                             |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                 |                             |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                 |                             |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                 |                             |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                 |                             |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                 |                             |  |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                 |                             |  |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                 |                             |  |  |  |  |  |
| Attachment(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                 |                             |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  4) Interview Summary (PTO-413) Paper No(s)/Mail Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                 |                             |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/17/2003.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 5) 🔲 Notice of Informal Pa                                      | atent Application (PTO-152) |  |  |  |  |  |
| Paper No(s)/Mail Date 7/17/2003. 6) Uother:  S. Patent and Trademark Office                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                 |                             |  |  |  |  |  |

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## **DETAILED ACTION**

The restriction requirement on last Office Action is most in view of the amendment filed July 17, 2003 to cancel claims 1-13 and 28-36.

## Claims 14-27 and 37-44 are presented for Examination.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-27 and 37-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. (U.S.Patent No. 5,331,000) of record.

Young et al. teach a composition comprising optically pure R(-) ketoprofen as the active ingredient or a pharmaceutically acceptable salts in the amount of about 12.5mg to about 1000mg within Applicants' claimed amounts set forth in claims 17-19, 23-25 and 38-43. (abstract, column 7, lines 34-40, claims). Young et al. teach the composition is suitable for oral administration may be presented as discrete units such as capsules or tablets (solid) set forth in Applicants' claims 16, 26 and 27. (column 7, lines 8-15). Young et al. teach the composition contains at least 90% by weight of R(-)

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ketoprofen and 10% by weight or less of the corresponding S(+) ketoprofen which reads and encompasses Applicants' claims 20-22. (column 5, lines 15-19). Young et al. teach the composition preferably contains at least 99% by weight of R(-) ketoprofen and 1% or less of the corresponding S(+) ketoprofen reads on Applicants' claim 22. (column 5, lines 19-30).

Applicants' recitation in claims an intended use of treating tinnitus or rining in the ear or a specific types of pain does not represent a patentable limitation since such fails to impart any physical limitation to the very same composition taught by Young et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan Supervisory Examiner

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Jmk July 22, 2004